

IRB Number:	09-1344	Legacy ID:	
PI:	Tina Stevens	IRB:	Biomedical
Sponsor:	US Environmental Protection Agency - Contracts		
Study Title:	Cardiopulmonary Responses to Exposure to Ozone and Diesel Exhaust With Moderate Exercise in Healthy Adults		

Certified: 09/30/2010

Reference ID: 1938

>> Brief Description of Event

After 2 consecutive days of O3 exposure, subject had a 43 & 58% decrement in FVC and FEV1, respectively, but returned to normal by next day. This decrement normally occurs in ~3-5% for this age group.

A1) Did this event occur at a site for which a UNC-CH IRB has direct oversight responsibility or involve a research participant at one of those sites? Yes

A2) Was the event unexpected in nature, severity, or frequency? No

Based on your response, this event is not required to be reported to this IRB. In lieu of reporting external adverse events from sites for which a UNC-CH IRB does not have direct oversight, the investigator should provide a written summary report to the IRB once the information has been reviewed by a data safety monitoring board (DSMB) or other oversight committee.

>> Attachments

There are no attachments for this event